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The American College of Obstetricians and Gynecologists

Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory | December 2020

Last updated March 4, 2021

This Practice Advisory was developed by the American College of Obstetricians and Gynecologists' Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group in collaboration with Laura E. Riley, MD; Richard Beigi, MD; Denise J. Jamieson, MD, MPH; Brenna L. Hughes, MD, MSc; Geeta Swamy, MD; Linda O'Neal Eckert, MD; Mark Turrentine, MD; and Sarah Carroll, MPH.

Summary of Key Information and Recommendations

COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

- The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the following vaccines:
  - Pfizer-BioNtech mRNA vaccine (BNT162b2): for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart.
  - Moderna mRNA-1273 vaccine: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.
  - Janssen Biotech, Inc. (Johnson & Johnson) Ad26.COV2.S vaccine: for use in individuals age 18 and older as a single dose regimen.
- After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19 (CDC 2020), the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years (CDC 2020), and the use of the Janssen (Johnson & Johnson) COVID-19 vaccine in persons aged ≥ 18 years (CDC 2021).
- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals.
- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:
  - the level of activity of the virus in the community
  - the potential efficacy of the vaccine
  - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
  - the safety of the vaccine for the pregnant patient and the fetus.

- While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.
- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, limited safety data specific to use in pregnancy is available. See details about the Food and Drug Administration's (FDA) EUA process below.
- Similar to their non-pregnant peers, vaccination of pregnant individuals with a COVID-19 vaccine may occur in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
- Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.
- Unfounded claims linking COVID-19 vaccines to infertility have been scientifically disproven. ACOG recommends vaccination for all eligible people who may consider future pregnancy.
- Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.
- Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.

COVID-19 Infection Risk in Pregnancy

Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers (Ellington MMWR 2020, Collin 2020, Delahoy MMWR 2020, Panagiotakopoulos MMWR 2020, Zambrano MMWR 2020). Although the absolute risk for severe COVID-19 is low, these data indicate an increased risk of ICU admission, need for mechanical ventilation and ventilatory support (ECMO), and death reported in pregnant women with symptomatic COVID-19 infection, when compared with symptomatic non-pregnant women (Zambrano MMWR 2020). Pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness consistent with the general population with similar comorbidities (Ellington MMWR 2020, Panagiotakopoulos MMWR 2020, Knight 2020, Zambrano MMWR 2020). Given the growing evidence, CDC has included pregnancy as a factor that leads to increased risk for severe COVID-19 illness (CDC). Similar to the general population, Black and Hispanic individuals who are pregnant have disproportionately higher rates of COVID-19 infection and death (Ellington MMWR 2020, Moore MMWR 2020, Zambrano MMWR 2020). Further, risk (Zambrano MMWR 2020) of ICU admission was higher for pregnant Asian and Native Hawaiian/Pacific Islander individuals. These disparities are due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, occupational exposure, systemic racism, and historic and continued inequities in the health care system.

COVID-19 Vaccines in Development

It is important to note that COVID-19 vaccine development and regulatory approval is a rapidly changing process, and information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations.

Advisory Committee on Immunization Practices Recommendations

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on how to use vaccines to control disease in the United States. The Committee's recommendations are sent to CDC's Director for approval. Once the ACIP recommendations have been reviewed and approved by the CDC Director and the U.S. Department of Health and Human Services, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population (ACIP).

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ACOG has representation on the ACIP, including on the ACIP COVID-19 working groups. ACIP has made the following recommendations for prioritization of COVID-19 vaccine allocation:

Phase 1a: Health care workers and long-term care facility residents (CDC 2020)
Phase 1b: Persons aged ≥75 years and frontline essential workers (CDC 2020)
Phase 1c: Persons aged 65-75 years, persons aged 16-64 years with high-risk* medical conditions (including pregnancy), and other essential workers (CDC 2020)
Phase 2: All other persons aged ≥16 years not already recommended for vaccination in Phases 1a, 1b, or 1c (CDC 2020)

*High-risk medical conditions outlined by the CDC include:

- Pregnancy
- Cancer
- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Down Syndrome
- Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2)
- Severe Obesity (BMI ≥ 40 kg/m2)
- Sickle cell disease
- Smoking (current or history)

- Type 2 diabetes mellitus

Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand (ACIP Slides 2020).

After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19 (CDC 2020), the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years (CDC 2020), and the use of the Janssen (Johnson & Johnson) COVID-19 vaccine in persons ≥ 18 years (CDC 2021). Information for pregnant and lactating individuals has been posted on CDC's website under Clinical Considerations. Within these clinical considerations, CDC outlines that a pregnant individual may choose to receive a COVID-19 vaccine. A discussion with their healthcare professional can help the patient make an informed decision, but is not required. Further, CDC states that lactating individuals may choose to be vaccinated.

U.S. FDA Emergency Use Authorization and Approval

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the following vaccines:

- **Pfizer-BioNtech mRNA vaccine (BNT162b2)**: for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart.
- **Moderna mRNA-1273 vaccine**: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.
- **Janssen Biotech Inc. (Johnson & Johnson)** monovalent vaccine (Ad26.COV2.S): for use in individuals age 18 years and older as a single dose regimen.

According to the EUA Fact Sheet for Health Care Professionals for Pfizer-BioNtech, Moderna, and Janssen COVID-19 vaccines, available data on COVID-19 vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. The EUA Fact Sheet for Recipients and Caregivers for these three vaccines states "If you are pregnant or breastfeeding, discuss your options with your healthcare provider." The EUA authority allows the FDA to strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives (FDA 2017).

Data on the safety and effectiveness of the vaccine(s) continues to be collected during the EUA period. (FDA 2017).

Vaccine Information and Recommendations

At the time of this publication, three vaccines developed for the prevention of COVID-19 have received EUA from the FDA. However, COVID-19 vaccines are rapidly emerging and additional EUAs are likely to materialize. ACOG will strive to update this guidance as quickly as possible while maintaining accurate, evidence-based information.

mRNA COVID-19 Vaccines (Pfizer-BioNtech & Moderna)

The development and use of mRNA vaccines is relatively new. These vaccines consist of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP) for delivery into the host cells. These vaccines utilize the body's own cells to generate the coronavirus spike protein (the relevant antigens), which, similar to all other vaccines, stimulates immune cells to create antibodies against COVID-19. The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes (CDC, Zhang 2019, Schlake 2012). Based on the mechanism of action of these vaccines and the demonstrated safety and efficacy in Phase II and Phase III clinical trials, it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in non-pregnant individuals. That said, there are no safety data specific to mRNA vaccine use in pregnant or lactating individuals and the potential risks to a pregnant individual and the fetus are unknown.

Adenovirus-vector Vaccines (Janssen Biotech Inc.)

The Janssen (Johnson & Johnson) COVID-19 vaccine (Ad26.COV2.S) is based on the AdVac® technology platform and is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector, constructed to encode a stabilized form of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) Spike (S) protein. The Ad26 vector cannot replicate following administration to humans, and available data demonstrate that it is cleared from tissues following injection (FDA 2021).

Ad26.COV2.S is not a live virus vaccine, it does not contain preservatives, and it does not replicate in the cells. Based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile, without significant safety issues identified to date. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern (FDA 2021).

Efficacy of COVID-19 Vaccines

All currently available COVID-19 vaccines have demonstrated high efficacy among their respective clinical trial endpoints. Vaccine efficacy is based on the time and place where the trials were conducted and the circulating SARS-CoV-2 virus(es). Direct comparison of the results of these trails is inappropriate at this time.

Efficacy of mRNA vaccines

Based on results from clinical trials, the Pfizer-BioNtech COVID-19 vaccine was 95% effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of previous infection (CDC).

Based on results from clinical trials, the Moderna vaccine was 94.1% effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of being previously infected (CDC).

Each of these vaccines appeared to have high efficacy in clinical trials among people of diverse age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Data on the efficacy specific to severe COVID-19, hospitalization, and death for these vaccines is limited at this time.

Efficacy of adenovirus-vector vaccines

Based on the results from clinical trials in the U.S., the Janssen COVID-19 vaccine has been shown to be 66.9% effective at preventing moderate/severe COVID-19 illness and 76.7% effective at preventing severe/critical COVID-19 illness after a single dose. This vaccine also demonstrated 93.1% effective at preventing hospitalizations 14 days following vaccination. (Janssen 2021)

Side Effects

Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.

Most study participants for both the Pfizer-BioNtech and Moderna vaccines experienced mild side effects similar to influenza-like illness symptoms following vaccination (see table below). In the Pfizer-BioNtech study subgroup of persons age 18-55 years fever greater than 38°C occurred in 3.7% after the first dose and 15.8% after the second dose (FDA 2020). In the Moderna vaccine trials, fever greater than 38°C was reported in 0.8% of vaccine recipients after the first dose, and 15.6% of vaccine recipients after the second dose (FDA 2020). Most of these symptoms resolved by day 3 after vaccination for both vaccines.

As is typical with adenovirus vaccines, side effects for the Janssen Biotech Inc. COVID-19 vaccine were generally mild and transient, resolving in 1-2 days following vaccination among safety study participants. In the Janssen Biotech Inc. safety study group, 9.0% of individuals receiving a COVID-19 vaccine experienced fever greater than 38°C following vaccination. Fever had a median duration of 1 day (FDA 2021).

Patients should be counseled about more severe side effects and when to seek medical care. For more information and details on side effects, see Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine from the CDC.

Table 1. Mild Side Effects Among All Study Participants*

	Moderna
	91.6%
	68.5%
	43.4%
	59.6%
	44.8%
	63%

	Pfizer-BioNTech
	84.1%

84.10%
62.90%
31.90%
38.30%
23.60%
55.10%

Janssen Biotech Inc.
48.6%
38.2%
N/A
33.2%
N/A
38.9%

**Fever was the least common side effect reported; see text above for data on frequency of fever*

Allergic Reactions Including Anaphylaxis

Allergic reactions including anaphylaxis have been reported to be rare following COVID-19 vaccination in non-pregnant individuals. For the Pfizer-BioNtech vaccine, through January 18, 2021, nearly 10 million doses were administered and monitoring by the Vaccine Adverse Event Reporting System detected 47 cases (4.7 cases per million doses administered) of anaphylaxis following vaccination (ACIP Slides). For the Moderna vaccine, through January 18, 2021, over 7.5 million doses were administered, and monitoring by the Vaccine Adverse Event Reporting System detected 19 cases (2.5 cases per million doses administered) of anaphylaxis following vaccination (ACIP Slides).

Anaphylaxis was not reported among any of the clinical trial participants for the Janssen COVID-19 vaccine. Allergic reactions and anaphylaxis rates will be monitored for the Janssen COVID-19 vaccine and information will be updated as soon as it is available (FDA 2021).

If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as non-pregnant individuals (eg, rapidly assess airway, breathing, circulation, and mental activity; call for emergency medical services; place the patient in a supine position, and administration of epinephrine) (CDC). Similar to non-pregnant individuals, anaphylaxis may recur after the individual begins to recover, and monitoring in a medical facility for at least several hours is advised, even after complete resolution of symptoms and signs.

For more information on the management of anaphylaxis after COVID-19 vaccination, see CDC's website.

Available Safety Information Related to the use of COVID-19 Vaccines in Pregnancy

Despite ACOG's persistent advocacy for the inclusion of pregnant individuals in COVID-19 vaccine trials, none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals. However, studies in pregnant women have begun or are planned.

Developmental and Reproductive Toxicity Data

Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech COVID-19 vaccine have been reported in Europe. According to the report presented to the European Medicines Agency, animal studies using the Pfizer/BioNtech COVID-19 vaccine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development (EMA).

A combined developmental and perinatal/postnatal reproductive toxicity (DART) study of Moderna's mRNA-1273 in rats was submitted to FDA on December 4, 2020. FDA review of this study concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention (FDA).

In a reproductive developmental toxicity study female rabbits were administered 1 mL of the Janssen COVID-19 Vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on Gestation Days 6 and 20 (i.e., one vaccination during early and late gestation, respectively). No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed (FDA 2021). Further, based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile, without significant safety issues identified to date. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern (FDA 2021).

These DART studies provide the first safety data to help inform the use of the vaccine in pregnancy until there are more data in this population.

Among participants of Phase II/III COVID-19 vaccine clinical studies in non-pregnant adults, a few inadvertent pregnancies that have occurred are being followed to collect safety outcomes.

V-safe and V-safe Pregnancy Registry Data

As of February 16, 2021, there have been over 30,000 pregnancies reported in CDC's v-safe post-vaccination health checker (CDC 2021). Based on limited self-reported information, no specific safety signals have been observed in pregnant people enrolled in v-safe; however longitudinal follow-up is needed.

CDC is currently enrolling pregnant individuals in a v-safe pregnancy registry and as of February 19, 2021 over 1,800 pregnant individuals were enrolled. Data collected through February 18th from the v-safe pregnancy registry indicate that the reactogenicity profile and adverse events observed among pregnant individuals in v-safe did not indicate any safety concerns. Additionally, side effects were similar in pregnant and non-pregnant populations. Specific pregnancy outcome data for 275 completed pregnancies are included in Table 2. As demonstrated below, no differences have been seen when comparing pregnant women participating in

the v-safe pregnancy registry with the background rates of adverse pregnancy outcomes.

Table 2. V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021

Miscarriage (<20 weeks)	26% 15%
Stillbirth (≥20 weeks)	0.6% 1%
Gestational diabetes	7-14% 10%
Preeclampsia or gestational hypertension	10-15% 15%
Eclampsia	0.27% 0%
Intrauterine growth restriction	3-7% 1%
Preterm birth	10.10% 10%

Congenital anomalies	
3%	
4%	
Small for gestational age	
3-7%	
4%	
Neonatal death	
0.38%	
0%	

Source: Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP). Atlanta, GA: Centers for Disease Control and Prevention; 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf. Retrieved March 1, 2021.

Evidence gathered through these systems will provide clinicians with critically needed data to inform future recommendations related to COVID-19 vaccination during pregnancy (ACIP slides).

ACOG Recommendations

Pregnant Individuals

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals. While safety data on the use of COVID-19 vaccines in pregnancy are limited, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals were generated from DART studies for the Pfizer-BioNtech, Moderna, and Janssen COVID-19 vaccines. Therefore, in the interest of patient autonomy, ACOG recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care

COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, written permission or documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include the level of activity of the pandemic in the community, the potential efficacy of the vaccine, the potential risk and severity of maternal disease, including the effects of disease on the fetus and newborn, and the safety of the vaccine for the pregnant patient and the fetus. While a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.

Clinicians should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated in the context of the individual patient's current health status, and risk of exposure, including the possibility for exposure at work or home and the possibility for exposing high-risk household members. Conversations about risk should take into account the individual patient's values and perceived risk of various outcomes and should respect and support autonomous decision-making (ACOG 2013).

Vaccination Considerations

- Similar to their non-pregnant peers, vaccination of pregnant individuals with a COVID-19 vaccine may occur in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations. Precautions should be discussed with any individual who reports a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines or polysorbate) (CDC). Locations administering COVID-19 vaccines should adhere to CDC guidance for use of COVID-19 vaccines, including screening recipients for contraindications and precautions, having the necessary supplies available to manage anaphylaxis, implementing the recommended postvaccination observation periods, and immediately treating suspected cases of anaphylaxis with intramuscular injection of

observation periods, and immediately treating suspected cases of anaphylaxis with intramuscular injection of epinephrine (CDC)

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.
- There is currently no preference for the use of one COVID-19 vaccine over another except for 16-17 year olds who are only eligible for the Pfizer-BioNtech vaccine.
- Individuals who receive either the Pfizer-BioNtech or Moderna COVID-19 vaccine should complete their 2-dose series with the same vaccine product.
- COVID-19 vaccines should not be administered within 14 days of receipt of another vaccine. For pregnant individuals, vaccines including Tdap and influenza should be deferred for 14 days after the administration of COVID-19 vaccines.
- Anti-D immunoglobulin (i.e. Rhogam) should not be withheld from an individual who is planning or has recently received a COVID-19 vaccine as it will not interfere with the immune response to the vaccine.

Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.

Pregnant individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's v-safe program (see below for more information on CDC's v-safe program).

Lactating Individuals

ACOG recommends COVID-19 vaccines be offered to lactating individuals. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving

Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine (ABM 2020).

Individuals Contemplating Pregnancy

Vaccination is strongly encouraged for non-pregnant individuals. Further, ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

Importantly, unfounded claims linking COVID-19 vaccines to infertility have been scientifically disproven. ACOG recommends vaccination for all eligible people who may consider future pregnancy. Given the mechanism of action and the safety profile of the mRNA vaccines in non-pregnant individuals, COVID-19 mRNA vaccines are not a cause of infertility. Adenovirus vector vaccines such as the Janssen COVID-19 vaccine cannot replicate following administration, and available data demonstrate that it is cleared from tissues following injection. Because it does not replicate in the cells, the vaccine cannot cause infection or alter the DNA of a vaccine recipient and is also not a cause of infertility (Evans, 2021).

If an individual becomes pregnant after the first dose of a COVID-19 vaccine requiring two doses (Pfizer-BioNtech or Moderna), the second dose should be administered as indicated. If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's v-safe program should be encouraged (see below for more information on CDC's v-safe program).

Importantly, routine pregnancy testing is not recommended prior to receiving any EUA-approved COVID-19 vaccine.

Health Equity Considerations and Communities of Color

Communities of color have been disproportionately affected by the COVID-19 pandemic. Individuals in communities of color are more likely to have severe illness and even die from COVID-19 likely due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, and occupational exposure, systemic racism, and historic and continued inequities in the health care system. Access to and confidence in COVID-19 vaccines is of critical importance for all communities, but willingness to consider vaccination varies by patient context, in part due to historic and continued injustices and systemic racism that has eroded trust in some communities of color. According to a recent Kaiser Family Foundation survey, only 50% of Black Americans compared with 65% of White Americans, would definitely or probably get vaccinated against COVID-19 even if the vaccine was free and determined safe by scientists, many citing distrust as a concern (Hamel 2020). When discussing COVID-19 vaccines with an individual who expresses concerns, it is critical to:

- Be aware of historical and current injustices perpetuated on communities of color
- Actively listen to and validate expressed fears and concerns
- Continue to support patients who decide not to be vaccinated, share resources, and encourage the continued use of prevention measures

If the patient is amenable to further discussion:

- Inform about the testing process, existing safety data and continued monitoring of safety and efficacy data on COVID-19 vaccines; there have not been shortcuts with the testing of this vaccine
- Discuss the increased incidence of infection and severe illness from COVID-19 in communities of color
- Note that individuals from communities of color were included in clinical trials (9.8% of Pfizer-BioNtech overall Phase II/III participants were Black and 26.2% were Hispanic/Latinx; 9.7% of Moderna overall Phase II/III participants were Black and 20% were Hispanic/Latinx; 13% of Janssen overall Phase II/III participants were Black and 14.7% were Hispanic/Latinx) and the vaccine was equally effective among different demographics, including race and ethnicity

Hispanic, Latinx) and the vaccine was equally effective among different demographics, including race and ethnicity

Additional Health Equity Resources

- Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html. Retrieved December 13, 2020
- Chandler R, Guillaume D, Parker AG, Mack A, Hamilton J, Dorsey J, et al. The impact of COVID-19 among Black women: evaluating perspectives and sources of information [published online November 5, 2020]. Ethn Health. DOI: 10.1080/13557858.2020.1841120. Available at: https://www.tandfonline.com/doi/full/10.1080/13557858.2020.1841120. Retrieved December 11, 2020.
- Silverman E. STAT-Harris poll: the share of Americans interested in getting Covid-19 vaccine as soon as possible is dropping. STAT. October 19, 2020. Available at: https://www.statnews.com/pharmalot/2020/10/19/covid19-coronavirus-pandemic-vaccine-racial-disparities/. Retrieved December 11, 2020.
- Joint statement on ensuring racial equity in the development and distribution of a COVID-19 vaccine. Health Leads blog. October 26, 2020. Available at: https://healthleadsusa.org/communications-center/blog/joint-statement-on-covid19-vaccine-equity/ . Retrieved December 11, 2020.
- American College of Obstetricians and Gynecology. Addressing health equity during the COVID-19 pandemic. Position Statement. Washington, DC: ACOG; 2020. Available at: https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2020/addressing-health-equity-during-the-covid-19-pandemic. Retrieved December 11, 2020.

Vaccine Confidence

Vaccine hesitancy, particularly around COVID-19 vaccines, exists among all populations. When communicating with patients it is extremely important to underscore the general safety of vaccines and emphasize the fact that no steps were skipped in the development and evaluation of COVID-19 vaccines. This can be done by briefly highlighting the safety requirements of vaccines,

and ongoing safety monitoring even after vaccines are made available. The following are some messages to consider using when discussing COVID-19 vaccines with patients:

- Vaccines are one of the greatest public health achievements of the 20th century. Before the widespread use of vaccines, people routinely died from infectious diseases, several of which have since been eradicated thanks to robust immunization programs.
- Community members may interpret efficacy data to imply that the Janssen COVID-19 vaccine is inferior to other available vaccines. It is important to be clear that all available COVID-19 vaccines are highly effective. Individuals should receive any product that is made available to them and can be confident in the vaccine's ability to provide a high level of protection from COVID-19 illness.
- Several vaccines have safely been given to pregnant and lactating individuals for decades.
- Early safety data on COVID-19 vaccines administered during pregnancy do not reveal any safety concerns.
- The rigor of COVID-19 vaccine clinical trials with regards to monitoring safety and efficacy meet the same high standards and requirements as with a typical vaccine approval process.
- While there has been a worldwide attempt to develop COVID-19 vaccines rapidly, this does not mean that any safety standards have been relaxed. In fact, there are additional safety monitoring systems to track and monitor these vaccines, including real-time assessment.
- Side effects such as influenza-like-illness can be expected with these vaccines, however this is a normal reaction as the body develops antibodies to protect itself against COVID-19. COVID-19 vaccines cannot cause COVID-19 infection. It is important not to be dissuaded by these side effects, because in order to get the maximum protection against COVID-19, patients need two doses of the vaccine.
- Safety monitoring continues well beyond the EUA administration.
    - CDC's V-SAFE: A new active surveillance smartphone-based after-vaccination health checker for people who receive COVID-19 vaccines. V-safe will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. Information on pregnancy status at the time of vaccination

for health problems following COVID-19 vaccination. Information on pregnancy status at the time of vaccination and at subsequent follow up time points will also be collected. The system will provide telephone follow up to anyone who reports medically significant (important) adverse events or exposure to COVID-19 vaccines during pregnancy or periconception period. As of January 20, 2021, there have been over 15,000 pregnancies reported in CDC's v-safe after-vaccination health checker.

- Vaccine Adverse Event Reporting System (VAERS): A national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the CDC and the FDA. Healthcare professionals are encouraged to report any clinically significant adverse events following vaccination to VAERS, even if they are not sure if vaccination caused the event. In addition, we are anticipating that the following adverse events will be required to be reported to VAERS for COVID-19 vaccines administered under an Emergency Use Authorization (EUA):
  - Vaccine administration errors (whether associated with an adverse event or not)
  - Serious adverse events (irrespective of attribution to vaccination) (such as death, life-threatening adverse event, inpatient hospitalization)
  - Multisystem inflammatory syndrome (MIS) in children [if vaccine is authorized in children] or adults
  - Cases of COVID-19 that result in hospitalization or death
- CDC's National Healthcare Safety Network (NHSN): An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- Vaccines and Medications in Pregnancy Surveillance System (VAMPSS): A national surveillance system designed to monitor the use and safety of vaccines and asthma medications during pregnancy
- FDA is working with large insurer/payer databases on a system of administrative and claims-based data for surveillance and research
- Additional safety monitoring information can be found here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Additional Resources

- CDC Vaccination Considerations for People who are Pregnant or Breastfeeding https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
- Baystate Health & University of Massachusetts Medical School COVID-19 Vaccine Decision Tool https://foamcast.org/covidvacpregnancy/?fbclid=IwAR35gMR8Tdx-qEC2CBGAfNYiTMeRhw7W-x0eGjABEh8eqODTujv49bkuzwE
- Frequently Asked Questions about COVID-19 Vaccination https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
- CDC's Talking to Recipients about COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

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